

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Liu et al

Serial No. 09/046,833

Filed: March 24, 1998

Title: **VECTORS AND VIRAL VECTORS, AND  
PACKAGING CELL LINES FOR  
PROPOGATING SAME**

Group Art Unit: 1636

Examiner: David Guzo

527 Madison Avenue, 9<sup>th</sup> Floor  
New York, New York 10022  
March 17, 2004

**FILED VIA EXPRESS MAIL**

Mail Stop No-Fee Amendment  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

**SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT**  
**UNDER 37 C.F.R. §§1.56 & 1.97-1.98**

Dear Sirs:

Pursuant to the provisions of 37 C.F.R. §§1.97-1.98, and in full compliance with their duty of disclosure under 37 C.F.R. §1.56, Applicants, through their attorney, are bringing the following ten (10) documents to the attention of the U.S. Patent and Trademark Office and the Examiner handling their above-identified application:

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Serial No.: 09/046,833

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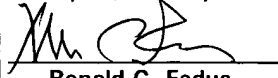
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**EXPRESS MAIL CERTIFICATE**

"Express Mail" Label No.: Ev042709983us

Deposit Date: March 17, 2004

I hereby certify that this paper and the attachments herein are being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 CFR 1.110 on the date indicated above and is addressed to the Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.



Ronald C. Fedus  
Reg. Exhibit 32,567

MAR 17 2004

Date

1. Dong, J., et al., International Patent Application No. WO 95/06743, published March 9, 1995 [EXHIBIT 1].
2. Emi, H., et al., "Pseudotype formation of murine leukemia virus with the G protein of vesicular stomatitis virus," Journal of Virology 65:1202-1207 (1991) [EXHIBIT 2].
3. Feng, M., et al., "Stable in vivo gene transduction via a novel adenoviral/retroviral chimeric vector," Nature Biotechnology 15:866-870 (1997) [EXHIBIT 3].
4. Fisher, K.J., et al., "A novel adenovirus-adeno-associated virus hybrid vector that displays efficient rescue and delivery of the AAV genome," Human Gene Therapy 7:2079-2087 (1996) [EXHIBIT 4].
5. Gerhardt, E., et al., "Phenotype mixing of rodent but not avian hepadnavirus surface proteins into human hepatitis B virus particles," Journal of Virology 69:1201-1208 (1995) [EXHIBIT 5].
6. Johnston, K.M., et al., "HSV/AAV hybrid amplicon vectors extend transgene expression in human glioma cells," Human Gene Therapy 8:359-370 (1997) [EXHIBIT 6].
7. Matano, T., et al., "Targeted infection of a retrovirus bearing a CD $\delta$ -Env chimera into human cells expressing human immunodeficiency virus type 1," Journal of General Virology 76:3165-3169 (1995) [EXHIBIT 7].
8. Vile, R.G., et al., "A murine cell line producing HTLV-1 pseudotype virions carrying a selectable marker gene," Virology 180:420-424 (1991) [EXHIBIT 8].
9. Wilson, J.M., et al., International Patent Application No. WO 96/13598, published May 9, 1996 [EXHIBIT 9].
10. Wong-Staal, F., et al., International Patent Application No. WO 96/36705, published November 21, 1996 [EXHIBIT 10].

The ten (10) foregoing references were cited in the Supplementary European Search Report (EP98915153, dated February 12, 2004).

A completed Form PTO-1449 listing the 10 above-submitted documents is also attached hereto as Exhibit 11.

By this voluntary citation of art, Applicants and their attorney are requesting that the documents be made of record in the present application.

The above citation of documents is not a representation that these documents constitute a complete or exhaustive listing, nor that the above listing necessarily includes the closest or most relevant documents, nor are these documents necessarily a complete listing of all documents known to Applicants or their attorney. It is simply a voluntary citation of documents made in good faith, which is not intended to serve in any way as a substitute for the Examiner's own search.

In view of the general and specific features described and claimed in the present application, Applicants respectfully submit that the present invention is neither disclosed nor suggested by the documents referred to above and is thus patentably distinct thereover. Furthermore, Applicants do not believe, and do not submit, by the citation of these references, that these documents, either by themselves or in combination with other documents, render the invention *prima facie* obvious under the duty of disclosure rules.

Applicants respectfully request that the Examiner make the above-submitted documents of record in the instant application. Applicants further request that the Examiner consider these documents as any of them may relate to the instant application.

It is believed that there is no fee or fees due in connection with this paper as all items were cited in a communication from a foreign patent office in a

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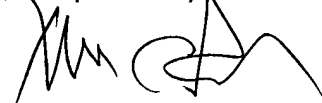
Serial No.: 09/046,833

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counterpart foreign application not more than three months prior to the filing of this Information Disclosure Statement. In the event that any fee or fees are due, however, the Patent and Trademark Office is hereby authorized to charge the amount of any such fee to Deposit Account No. 05-1135, or to credit any overpayment thereto.

Respectfully submitted,



Ronald C. Fedus  
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Natalie Bogdanos  
Registration No. 51,480  
Attorneys for Applicants

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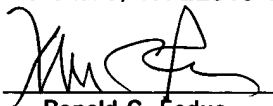
Title: VECTORS AND VIRAL VECTORS AND PACKAGING CELL LINES FOR  
PROPOGATING SAME

TRANSMITTAL  
INFORMATION DISCLOSURE STATEMENT

Mail Stop No-Fee Amendment  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

Transmitted herewith is an Information Disclosure Statement which is being filed in accordance with 37 C.F.R. §§ 1.56 and 1.97-1.98. The items listed on Form PTO-1449, a copy of which is enclosed, may be deemed to be pertinent to the above-identified application and are made of record to assist the Patent and Trademark Office in its examination of this application. The Examiner is respectfully requested to fully consider the items and to independently ascertain their teaching.

EXPRESS MAIL CERTIFICATE	
"Express Mail" Label No.:	<u>EV042709983US</u>
Deposit Date:	<u>March 17, 2004</u>
I hereby certify that this paper and the attachments herein are being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 CFR 1.110 on the date indicated above and is addressed to the Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.	
 Ronald C. Fedus Reg. Exhibit 32,567	<u>MAR 17 2004</u> Date

Enz-56(D4)

1. ☐ For each of the following items listed on the enclosed copy of Form PTO-1449 that is not in the English language, an English language translation of that item or a portion thereof or a concise explanation of the relevance of that item is enclosed:
2. ☐ For each of the following items listed on the enclosed copy of form PTO-1449 that is not in the English language, a concise explanation of the relevance of that item is incorporated in the specification of the above-identified application.
3. ☐ Any copy of the items on the enclosed copy of Form PTO-1449 that is not enclosed with this Information Disclosure Statement was previously cited by or submitted to the Patent and Trademark Office in the prior ☐ Divisional or ☐ Continuation-In-Part application under 37 C.F.R. §1.60, U.S. Serial No. \_\_\_\_\_, filed \_\_\_\_\_.
4. ☐ No fee is due under 37 C.F.R. §1.17(p) for this Information Disclosure Statement since it is being filed in compliance with:
  - ☐ 37 C.F.R. §1.97(b)(1), within three months of the filing date of the above-identified application.
  - ☐ 37 C.F.R. §1.97(b)(2), within three months of the date of entry into the national stage as set forth in §1.491 in an international application.
  - ☐ 37 C.F.R. §1.97(b)(3), before the mailing date of a first Office action on the merits.
5. ☐ No fee is due under 37 C.F.R. §1.17(p) for this Information Disclosure Statement since it is being filed in compliance with 37 C.F.R. §1.97(c), after the period specified in paragraph 4 above but before the mailing date of a final action or a Notice of Allowance (where there has been no prior final action), and is accompanied by one of the certifications pursuant to 37 C.F.R. §1.97(e) set forth in paragraph 9 below.
6. ☐ A fee is due under 37 C.F.R. §1.17(p) for this Information Disclosure Statement since it is being filed in compliance with 37 C.F.R. §1.97(c), after the period specified in paragraph 4 above but before the mailing date of a final action or a notice of allowance (where there has been no prior final action):
  - ☐ A check in the amount of \$180.00 is enclosed in payment of the fee.

☐ Charge the fee to Deposit Account No. 05-1135, Order No. ENZ-56. A DUPLICATE COPY OF THIS SHEET IS ATTACHED.

7. ☐ A fee is due under 37 C.F.R. §1.17(i)(1) for this Information Disclosure Statement since it is being filed in compliance with 37 C.F.R. §1.97(d), after the mailing date of a final action or a notice of allowance, whichever comes first, but before payment of the issue fee, and is accompanied by:
- a. one of the certification pursuant to 37 C.F.R. §1.97(e) set forth in paragraph 9 below; and
  - b. the attached petition requesting consideration of this Information Disclosure Statement; and
  - c. the fee due under 37 C.F.R. §1.17(i)(1) which is paid as set forth in paragraph 10 below.
8. ☐ A fee is due under 37 C.F.R. §1.17(i)(1) for this Information Disclosure Statement since it is being filed in compliance with:
- a. ☐ 37 C.F.R. §1.313(b)(3), after the issue fee has been paid and information cited in this Information Disclosure Statement may render at least one claim unpatentable and is accompanied by the attached Petition To Withdraw Application From Issue;
  - b. ☐ 37 C.F.R. §1.313(b)(5), after the issue fee has been paid and information cited in this Information Disclosure Statement is to be considered in a Continuation application upon abandonment of the instant application and is accompanied by the attached Petition To Withdraw Application From Issue.
  - c. ☐ The fee due under 37 C.F.R. §1.17(i)(1) is paid as set forth in paragraph 10 below.
9. ☒ I hereby certify that each item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Information Disclosure Statement.
- ☐ I hereby certify that no item of information in the Information Disclosure Statement filed herewith was cited in a communication from a foreign patent office in a counterpart foreign application or, to my knowledge after making reasonable inquiry, was known to any individual designated in §1.56(c) more than three months prior to the filing of this Information Disclosure Statement.

**Enz-56(D4)**



10. ☐ A check in the amount of \$180.00 is enclosed in payment of the fee due under 37 C.F.R. §1.17(i)(1).

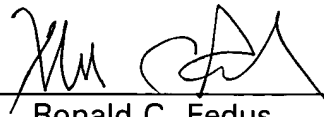
☐ Charge the fee under 37 C.F.R. §1.17(i)(1) to Deposit Account No. 05-1135. Order No. ENZ-56. A DUPLICATE COPY OF THIS SHEET IS ATTACHED.

☒ The Commissioner is hereby authorized to charge any additional fees which may be required for this Information Disclosure Statement, or credit any overpayment to Deposit Account No. 05-1135. A DUPLICATE COPY OF THIS SHEET IS ATTACHED.

Respectfully submitted,

Dated: March 17, 2004

By:



Ronald C. Fedus  
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Natalie Bogdanos  
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**Enz-56(D4)**

Form PTO-1449 U.S. Department of Commerce

(REV. 8-83) Patent and Trademark Office

INFORMATION DISCLOSURE CITATION  
(use several sheets if necessary)Atty. Docket No.  
ENZ-56(D4)

Serial No. 09/046,833

Applicants: Liu, et al

Filed: March 24, 1998

Group: 1636

## U.S. PATENT DOCUMENTS

EXAMINER INITIAL	DOCUMENT NUMBER	DATE	NAME	CLASS	SUB CLASS	FILING DATE IF APPRO- PRIATE

## FOREIGN PATENT DOCUMENTS

DOCUMENT NUMBER	DATE	NAME	CLASS	SUB CLASS	TRAN- SLATION YES NO
WO 9 5 0 6 7 4 3	3/9/95	Dong, et al			
WO 9 6 1 3 5 9 8	5/9/96	Wilson, et al			
WO 9 6 3 6 7 0 5	11/21/96	Wong-Staal, et al			

## OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

	Emi, H., et al., "Pseudotype formation of murine leukemia virus with the G protein of vesicular stomatitis virus," <u>Journal of Virology</u> 65:1202-1207 (1991)
	Feng, M., et al., "Stable in vivo gene transduction via a novel adenoviral/retroviral chimeric vector," <u>Nature Biotechnology</u> 15:866-870 (1997)
	Fisher, K.J., et al., "A novel adenovirus-adenovirus-associated virus hybrid vector that displays efficient rescue and delivery of the AAV genome," <u>Human Gene Therapy</u> 7:2079-2087 (1996)
	Gerhardt, E., et al., "Phenotype mixing of rodent but not avian hepadnavirus surface proteins into human hepatitis B virus particles," <u>Journal of Virology</u> 69:1201-1208 (1995)
	Johnston, K.M., et al., "HSV/AAV hybrid amplicon vectors extend transgene expression in human glioma cells," <u>Human Gene Therapy</u> 8:359-370 (1997)
	Matano, T., et al., "Targeted infection of a retrovirus bearing a CD8-Env chimera into human cells expressing human immunodeficiency virus type 1," <u>Journal of General Virology</u> 76:3165-3169 (1995)
	Vile, R.G., et al., "A murine cell line producing HTLV-1 pseudotype virions carrying a selectable marker gene," <u>Virology</u> 180:420-424 (1991)

EXAMINER

DATE CONSIDERED

\*EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

